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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/723,908   | 11/26/2003  | Peter Andersen       | 0459-0752P          | 5514             |
| 2292   | 7590        | 08/21/2008           | EXAMINER            |                  |
| BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      |                     | SWARTZ, RODNEY P |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
|  |             | 1645                 |                     |                  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |             |                      | 08/21/2008          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                         |                     |  |
|------------------------------|-------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>  | <b>Applicant(s)</b> |  |
|                              | 10/723,908              | ANDERSEN ET AL.     |  |
|                              | <b>Examiner</b>         | <b>Art Unit</b>     |  |
|                              | Rodney P. Swartz, Ph.D. | 1645                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20May2008.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12, 14-18 and 27-50 is/are pending in the application.
- 4a) Of the above claim(s) 28-45 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12, 14-18, 27 and 46-50 is/are rejected.
- 7) Claim(s) 1-3 is/are objected to.
- 8) Claim(s) 1-12, 14-18 and 27-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

**Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 May 2008 has been entered.

Claims 1, 2, and 3 have been amended. Claim 51 has been canceled.

2. Claims 1-12, 14-18, and 27-50 are pending. Claims 28-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 1-12, 14-18, 27, and 46-50 are under consideration.

**Rejections Withdrawn or Moot**

4. The rejection of claim 51 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunologically equivalent" is moot in light of the cancelation of the claim.

5. The rejection of claim 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot in light of the cancelation of the claim.

**Rejections Maintained**

6. The rejection of claims 1-12, 14-18, 27 and 46-50 under 35 U.S.C. 112, second paragraph, as being indefinite for "immunologically equivalent" is maintained.

Applicants argue that in light of the teachings of the specification, "immunologically equivalent" is clear.

The examiner has considered applicants' argument, but does not find it persuasive because the claims remain drawn to a substantially pure polypeptide of any length (a longer polypolypeptide) and the specification does not define the term for this type of embodiment.

### **Claim Objections**

7. Claims 1, 2, and 3 are objected to because of the following informalities: line 2 "peptide" should be "peptide". Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 1-12, 14-18, 27 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 2, and 3 are drawn to a substantially pure polypeptide selected from a group consisting of defined number of amino acid, and "a longer polypeptide".

It is unclear what are the metes and bounds of "a longer polypeptide". The specification does not define the term. Claims 4-12, 14-18, and 46-50 depend from the claims, but do not clarify the matter.

### **Conclusion**

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 3, 2008

|  |                         |   |
|--|-------------------------|---|
| <b>Application Number</b><br> | Application/Control No. | Applicant(s)/Patent under Reexamination |
|  | 10/723,908              | ANDERSEN ET AL.                         |
| Examiner   | Art Unit                |   |
| Rodney P. Swartz, Ph.D.  | 1645                    |   |